

## REMARKS

Applicants wish to thank the Examiner for reviewing the present patent application.

### I. Rejection Under 35 USC §112, Second Paragraph

Applicants acknowledge and appreciate that the antecedent basis rejection of claim 1 has been withdrawn.

The Examiner maintains the rejection of claims 1 and 4-9 under 35 USC §112, second paragraph with respect to the term "solid asymmetric particles". In the rejection the Examiner again alleges that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Particularly, the Examiner mentions that the limitation "solid asymmetric particles" is unclear.

Applicants wish to again respectfully point out that solid asymmetric particles are clear and not indefinite. In fact, at page 5 of the specification, lines 10-11, Applicants point out that the solid asymmetric particles may be particles of a fatty acid containing from 12 to 22 carbon atoms, and they may optionally be crystalline. Thus, examples of the solid asymmetric particles are clearly described in the specification. Again, it is well settled that it is not a requirement for Applicants to have an example for every element covered in an independent claim. Moreover, use of "may" is certainly definite, suggesting illustrative non-limiting examples of the particles. In view of this, Applicants respectfully request that the rejection made under 35 USC §112, paragraph 2 be withdrawn and rendered moot.

## II. Rejection Under 35 USC §103

The Examiner has, again, rejected claims 1 and 4-9 (and newly filed claims 21-23) under 35 USC §103 as being unpatentable over Mitchnick et al., U.S. Patent No. 5,441,726 in view of Galley et al., U.S. Patent No. 5,609,852 and Halls, U.S. Patent No. 6,627,949 (hereinafter, '726, '852 and '949, respectively).

The Examiner, for a third time, continues to maintain the rejection of claims 1 and 4-9 under 35 USC §103 as being unpatentable over the '726 reference, in view of the '852 reference and the '949 reference. In the rejection, the Examiner continues to maintain, in summary, that the '726 reference discloses a creamy foundation composition that is prepared by mixing components in a manner suggested in column 13 of the '726 patent at lines 7-28. Particularly, the Examiner, again, relies on what is set forth in the '726 patent in the above defined column and lines and mentions that zinc oxide is dispersed in a solution of components 7-10 and heated to 75°C. The Examiner further mentions that components 1-6 (which contain 5% by wt. stearic acid) are mixed and heated to 80°C to form a solution which is then added to the solution containing zinc oxide to produce an emulsion. The Examiner finally concludes that the emulsion is cooled under stirring to 50°C and a final perfume ingredient is added.

Nevertheless, and again, the Examiner has clearly acknowledged that the '726 reference does not expressly teach heating a mixture of zinc oxide particles and stearic acid to a temperature of about 80°C for about 5 to about 10 minutes and that the '726 reference does not expressly disclose the addition of zinc oxide in an amount of about 1% to about 4% by weight of the cosmetic composition.

In an attempt to cure the vast deficiencies of the '726 reference, the Examiner continues to rely on the '852 reference which merely describes a sunscreen composition having titanium dioxide particles that have a dye lake precipitated onto their surface in a dye lake-titanium dioxide ratio of between 10:90 and 80:20.

The '949 reference, again, is relied on the rejection maintained wherein the Examiner mentions that the same describes nano-size ZnO particles in the preferred range of 0.5 to 15%. In view of the above, the Examiner believes that the rejection made under 35 USC §103 is warranted and should be maintained.

Notwithstanding the Examiner's apparent position to the contrary, it is the Applicants' position that the presently claimed invention is patentably distinguishable from the above-described for at least the following reasons.

As already made of record on numerous occasions, the present invention is directed to a process for incorporating zinc oxide particles in a cosmetic composition comprised of solid asymmetric particles, comprising:

- melting the solid asymmetric particles to form melted fatty acid;
- adding un-coated zinc oxide particles to the melted fatty acid to form a mixture of zinc oxide and fatty acid;
- heating the mixture to a temperature of less than about 80°C for about 5-10 minutes; and
- cooling the mixture to a temperature of about 50°C, thereby quenching any reaction between the zinc oxide and the fatty acid.

The invention of claim 1 is further defined by the dependent claims which claim, among other things, the zinc oxide particle size, that the solid asymmetric particles are comprised of stearic acid, that the solid asymmetric particles comprise about 10 to about 25% by weight of the composition, the specific heating temperature, and the conversion of the zinc oxide and fatty acid being controlled to a conversion of about 5% to about 10% of the zinc oxide. Claim 21 characterizes the asymmetric particles and claims 22 and 23 describe levels of ZnO particles used in the process.

As set forth in the present invention, zinc oxide is added to melted fatty acid. Moreover, zinc oxide is added to melted fatty acid leading to the formation of a zinc stearate shell on a zinc oxide nano-particle. The formation of the shell inhibits further reactions and allows for excellent dispersion within a cosmetic composition.

In contrast, and as set forth in the '726 reference, titanium oxide, talc, coloring pigment, and zinc oxide rods are pulverized. The resulting pulverized mixture is then dispersed in a solution having purified water, antiseptic, triethanolamine, and sorbitol. The resulting dispersion is heated to 75°C. A subsequent mixture of stearic acid, lipophilic glycerol monostearate, cetostearyl alcohol, propylene glycol monolaureate, squalane, and olive oil is then made and heated to 80°C to form a solution. The two solutions are combined and stirred to form an emulsion which is cooled to 50°C.

Certainly, zinc oxide is not added to a fatty acid comprising component first but to aqueous components. When a second component comprising stearic acid is added, no controlled contact (if any contact at all) will be made between the zinc oxide and fatty

acid. Moreover, it is not clear from the '726 reference what the temperature of the emulsion is after the aqueous components and oily components are combined. Furthermore, there is no teaching whatsoever in the '726 reference that even remotely suggests the time required to heat the mixture having fatty acid and zinc oxide. Again, and as already made of record, the present invention is patentably distinguishable over the '726 reference since the claimed invention is directed to a method for preparing a cosmetic composition comprising solid asymmetric particles, the method having a step where a mixture of zinc oxide and fatty acid is heated to a temperature of less than 80°C and the heating time is between 5 and 10 minutes. The addition of zinc oxide is at an amount such that about 0.1 to 10% by weight of the cosmetic composition prepared comprises zinc oxide. In fact, the composition made in the '726 reference is a creamy foundation, and such a composition would not be formed with the solid asymmetric particles defined according to the present invention.

In an attempt to cure the vast deficiencies of the '726 reference, the Examiner relies on the '852 reference which merely describes sunscreen having a dye lake precipitated onto its surface. The '949 reference is merely directed to a formulation of zinc oxide and at least one metal hydroxystearate in a synergistically effective amount. The sunscreen composition of the '949 reference is partly predicated on the unexpected discovery that when pigment grade zinc oxide is combined with magnesium aluminum hydroxystearate, the resulting sunscreen formulation does not retain the expected whiteness or pigmentation after application onto the skin. Secondly, the reference describes a composition that appears to show a synergistic enhancement of SBF rating provided by a sunscreen formulation containing zinc oxide and a metal hydroxy stearate. There is no teaching whatsoever in the '949 reference that even remotely suggests that solid asymmetric particles may be melted and combined with zinc oxide to thereby produce a mixture of zinc oxide and fatty acid.

Responding to the Examiner's final comments, Applicants wish to again point out that zinc oxide is not added to melted fatty acid in the primary reference of record.

In view of the above, it is clear that all the important and critical limitations set forth in the presently claimed invention are not found in the combination of references relied on by the Examiner. Therefore, it is clear that a *prima facie* case of obviousness has not been established and that the rejection made under 35 USC §103 is improper and must be withdrawn.

### III. Rejection Under 35 USC §103

Applicants appreciate the translation of WO 02/24153.

The Examiner has, again, rejected claims 1, 6, 8 (and newly filed claims 21-23) under 35 USC §103 as being unpatentable over Nishihama, WO 02/24153 (hereinafter, '153) where the Examiner maintains that the same is equivalent to U.S. Patent No. 6,949,248 (hereinafter, '298). In the rejection, the Examiner mentions, in summary, that claims 1, 6 and 8 are rendered obvious in view of the '153 reference wherein the Examiner concludes that a glycol, Beegum and water are stirred at a temperature of 70°C to create a water phase, and stearic acid, cetyl alcohol, petroleum, silicone oil, liquid petroleum, glyceryl monostearate and polyoxyethylene mono oleate are stirred and heated (to 70°C) with perfume and antiseptic to produce an oil phase. The Examiner maintains that powders including zinc white were added to the water phase after which

the resulting dispersion was added to the oil phase to contact zinc white with stearic acid to produce an emulsion that was ultimately cooled.

The Examiner has admitted that the '153 reference does not explicitly state heating times, but nevertheless, the Examiner believes that the heating times would be obvious to one of ordinary skill in the art. Thus, the Examiner believes, in view of the above, that the rejection made under 35 USC §103 is warranted.

Notwithstanding the Examiner's apparent position to the contrary, it is the Applicants' position again that the presently claimed invention is patentably distinguishable from the above-described for at least the following reasons.

As already made of record, independent claim 1 is directed to a process for incorporating zinc oxide into a cosmetic composition wherein solid asymmetric particles that are melted for form melted fatty acid are contacted with zinc oxide particles to form a zinc oxide and fatty acid mixture. The mixture is heated at specific temperatures for a specific time and cooled to produce a desired cosmetic composition. Claim 1 is further defined by the dependent claims, which claim, among other things, specific temperatures and that the solid asymmetric particles may comprise stearic acid. Claim 21 further defines the solid asymmetric particles as those which may contain solid asymmetric fatty acid and claims 22 and 23 define specific amounts of zinc oxide particles that may be used in the process.

Nevertheless, and again, the '248 reference is merely directed to a metal oxide/silica composite and a cosmetic preparation comprising such a composite. Column 8 at Table 4 of the '248 reference merely describes a cosmetic preparation whereby purified water is added to polyethylene glycol and Beegum to make an aqueous phase. Stearic acid, cetyl alcohol, petroleum, silicone oil, liquid petroleum, glyceryl monostearate and polyethylene mono oleate are mixed with perfume and antiseptic to make an oil phase. The zinc white is added to the water phase which is then added to an oil phase comprising stearic acid. There is no teaching whatsoever in the U.S. counterpart of the Japanese reference that even remotely suggest the addition of zinc oxide particles to melted fatty acid to form a mixture of zinc oxide and fatty acid. In fact, it is unclear (based on the teachings in the '248 reference) what, if any, zinc white and stearic acid contact there will be. In view of this, it is clear that all the important and critical limitations set forth in the presently claimed invention are not found in the references relied on by the Examiner, assuming that the '248 reference is identical to the '153 reference. In view of this, it is clear that a *prima facie* case of obviousness has not been established and that the rejections made to claims 1, 6, 8 and 21-23 should be withdrawn and rendered moot.

Responding to the Examiner's final comments, Applicants respectfully submit that the addition of  $Z_nO$  to melted fatty acid to form a mixture is not taught in the references relied on by the Examiner.

Applicants submit that all claims of record are now in condition for allowance. Reconsideration and favorable action are earnestly solicited.

Applicants further submit this case is ready for appeal and would appreciate an Examiner's answer if a second brief is filed.

In the event the Examiner has any questions concerning the present patent application, the Examiner is kindly invited to contact the undersigned as his earliest convenience.

Respectfully submitted,



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